

AGREEMENT BETWEEN
THE DEPARTMENT OF HEALTH AND HUMAN SERVICES
OF THE UNITED STATES OF AMERICA
AND
THE GENERAL ADMINISTRATION
OF QUALITY SUPERVISION, INSPECTION AND QUARANTINE
OF THE PEOPLE'S REPUBLIC OF CHINA
ON
THE SAFETY OF FOOD AND FEED

The Department of Health and Human Services ("HHS") of the United States of America ("United States") and the General Administration of Quality Supervision, Inspection and Quarantine ("AQSIQ") of the People's Republic of China ("China") (hereinafter referred to together as "the Parties"):

Understanding the mutual benefits of protecting the public health through bilateral cooperation and exchange between the Parties with regard to the safety of food and feed;

Appreciating the long-standing collaboration between the United States Food and Drug Administration of HHS ("HHS/FDA") and AQSIQ and the history of the AQSIQ registration and certification program;

Desiring to continue to work together to protect the safety and health of consumers and animals in the United States and the customs territory of China to prevent, intervene, and respond to any safety issues related to food and feed exported from one country to another;

Recognizing that such cooperation can improve and promote the health of people in the United States and in China, and enhance confidence in safety of food and feed exported from one country to another;

Have agreed as follows:

Article I

Purpose

The purpose of this Agreement is to establish a bilateral cooperative mechanism regarding food and feed safety. Such a mechanism may include current and future registration and certification systems. The mechanism aims to provide the Parties with information to use in judging whether an imported product meets the requirements of the importing country.

Article II

Definitions

For purposes of this Agreement, the following definitions shall apply.

1. "Covered Products" means food and feed under the jurisdiction of both Parties.
2. "Designated Covered Product" means a Covered Product that has been designated for inclusion in any phase of the cooperative mechanism regarding food and feed safety. Designated Covered Products are listed in the Annex.
3. "Feed" means articles under the jurisdiction of both Parties that are used for food or drink for animals other than humans, including articles used for components of such article and including vitamins or herbs meant to supplement the diet not regulated as drugs. Feed includes feed ingredients, feed additives, and feed that contains veterinary drugs, whether processed, semi-processed, or raw.
4. "Firm" means any business in either the customs territory of China or the United States that is engaged in the manufacture, production, growing,

processing, packing, testing, holding, transporting, distribution, or export of food or feed.

5. "Food" means articles under the jurisdiction of both Parties that are used for food or drink for humans, including articles used for components of any such article.
6. "HHS/FDA Requirement" means any U.S. law, regulation or other requirement, including any amendment adopted after the date of entry into force of this Agreement, concerning food or feed that is administered or enforced by HHS/FDA.
7. "AQSIQ/CNCA Requirement" means any Chinese law, regulation or other requirement, including any amendment adopted after the date of entry into force of this Agreement, concerning food or feed that is administered or enforced by AQSIQ or the Certification and Accreditation Administration ("AQSIQ/CNCA").
8. "AQSIQ/CNCA Registered Establishment" means an Establishment that AQSIQ/CNCA has registered meets Chinese relevant registration Laws/regulations and HHS/FDA Requirements pursuant to the Annex.
9. "HHS/FDA Registered Establishment" means an Establishment that has registered with HHS/FDA pursuant to the U.S. Federal Food, Drug, and Cosmetic Act under 21 U.S.C. 350d.
10. "Establishment" means any Firm's site or facility within the customs territory of China or in the United States that is engaged in the manufacture, producing, growing, processing, packing, testing, holding, transporting, distribution, or export of food or feed.

Article III

General Principles

1. The Parties shall engage in regulatory cooperation regarding the export of Covered Products from the customs territory of China to the United States and Covered Products produced in the United States and exported to the customs territory of China as set out in Article V and as further defined in Work Plans to be agreed upon by the Parties.
2. Each Party shall engage in information-sharing as set out in Article IV to improve its understanding of, and to gain greater confidence in, the other Party's regulatory system and as further defined in Work Plans to be agreed upon by the Parties. As specified in Article IV, each Party shall share relevant information with the other Party, including on laws, regulations, areas of jurisdiction, and public health and safety.
3. The Parties shall engage in regulatory cooperation regarding improving the safety of food and feed as set out in Articles IV and V and as further defined in Work Plans to be agreed upon by the Parties.
4. The Parties shall hold annual meetings between HHS/FDA and AQSIQ leaders to discuss and evaluate progress under this Agreement, among other things.

Article IV

Information Sharing

The Parties shall exchange information on their regulatory systems and other public-health matters concerning Covered Products as follows:

1. A Party may provide information to the other Party in the English or the Chinese language.
2. The Parties shall exchange copies of, and other relevant information concerning, their respective laws and regulations relating to food and feed safety.

3. Each Party shall immediately notify the other Party of significant risks to public health related to product safety, manufacturing conditions, recalls, and other instances that involve imminent or significant danger to health, or the gross deception of consumers with regard to Covered Products. Such notification shall occur within two (2) calendar days of the discovery of the significant risk to public health or gross deception of consumers. Each Party shall promptly respond to requests from the other Party for information concerning any such notification, including contact information for the Establishments or other entities concerned. Such response shall normally occur within five (5) calendar days of the request from the other Party unless otherwise specified in the Work Plan. The Work Plan shall include specific commitments to ensure the timeliness of any such notification or response.

Article V

Regulatory Cooperation

The Parties shall:

1. Develop and set out in the Work Plan strategies to control the transshipment of potentially unsafe Covered Products.
2. Develop appropriate regulatory cooperative activities, including training programs and scientific discussions or cooperation, intended to support the long-term stability and effectiveness of the registration and certification programs for Covered Products. For each training program or other cooperative activity that requires travel or other organizational costs, each Party shall bear its own costs of participation. Appropriate regulatory cooperative activities may include the following:
 - a. development of laboratory and risk-assessment methodologies, including performing analyses on request by the other Party;
 - b. work on identifying and discussing significant differences in maximum residue levels (MRLs) of veterinary drugs used in food-producing animals;

- c. exchange of scientific, technical, and regulatory information about compliance and enforcement programs of each Party;
 - d. identification of, and work on the mitigation and elimination of, significant human-health and animal-health concerns associated with the incidental or intentional chemical, radiologic, or microbiological contamination of human and animal foods (for example contamination with copper sulfate, dioxin or polychlorinated biphenyls);
 - e. identification of any substitution or addition of a substance to an ingredient in food or feed or to a food or feed product that reduces the quality of the ingredient or the product, or makes it appear of greater value than it is, when the substitution or addition has not been clearly revealed to the recipient; and
 - f. exchange of information regarding mandatory, pre-market review/approval processes for food ingredients.
3. Report any science and technology cooperation to the Joint Commission on Scientific and Technological Cooperation established under the Agreement Between the Government of the United States of America and the Government of the People's Republic of China on Cooperation in Science and Technology, signed at Washington January 31, 1979.
 4. Develop a streamlined process for facilitating (e.g., issuing a letter of invitation), no later than five (5) calendar days after receipt of a request from a Party, inspections of Establishments by the requesting Party. Such inspection may be conducted with or without providing advance notice (as specified in the request) to the Establishment concerned.
 5. Exchange their respective web links that identify requirements for import into their respective customs territories for Covered Products. Each Party shall post the web link of the other Party on its website within thirty (30) calendar days of receipt of the web link.

Article VI

Rights

1. For the purpose of using AQSIQ/CNCA registration and/or certification to inform decision-making regarding the admissibility of Covered Products for entry into the United States, both Parties shall endeavor to agree on all criteria and procedures that AQSIQ/CNCA uses to implement the registration and certification provisions of this Agreement. For greater certainty, all Covered Products offered for import into the United States shall be subject to HHS/FDA Requirements and all other relevant U.S. laws and regulations.
2. Both Parties shall endeavor to agree on all criteria and procedures that HHS/FDA uses to implement the registration obligations under this Agreement. For greater certainty, all Covered Products exported to the customs territory of China shall be subject to AQSIQ Requirements and all other relevant Chinese laws and regulations.
3. For greater certainty, nothing in this Agreement shall be construed to require a Party or any other relevant Government official to base any decisions on admission of any Covered Product on any list or other information the other Party may provide.

Article VII

Administration

1. Within fifteen (15) calendar days of the date of entry into force of this Agreement, each Party shall notify the other Party in writing of its primary points of contact for coordinating all bilateral activities under this Agreement, including coordinating meetings, exchanging information, and sending and receiving notifications.
2. The Parties hereby establish a Working Group. Within thirty (30) calendar days of the date of entry into force of this Agreement, each Party shall identify

relevant policy and technical experts of each Party to serve on the Working Group.

3. Within sixty (60) calendar days of the date of entry into force of this Agreement, the Working Group shall hold its first meeting to develop a Work Plan that:
 - a. further details the specific activities each Party shall perform pursuant to this Agreement within the first 12-month period following the date of entry into force of this Agreement and time lines for completion of each such activity; and
 - b. includes, as appropriate, performance measures to evaluate the success of each activity.
4. Within 120 calendar days of the date of entry into force of this Agreement, the Working Group shall finalize the Work Plan for the first 12-month period following the date of entry into force of this Agreement. The Parties shall assess the Work Plan at the conclusion of the 12-month period.
5. For each subsequent 12-month period, the Working Group shall meet to develop a Work Plan that further details specific activities that each Party shall perform pursuant to this Agreement within that period and, as appropriate, includes performance measures to evaluate the success of each such activity. The Parties shall assess each such Work Plan at the conclusion of the relevant period.
6. The Work Plan for each 12-month period, when adopted by the Parties, shall include binding commitments for the effective and timely implementation of this Agreement. Each Party shall make the Work Plan for the first twelve (12) months, and each subsequent year, publicly available on its respective website.
7. Within 180 calendar days of the date of entry into force of this Agreement, high level representatives of the Parties shall meet to discuss the implementation of and review progress under this Agreement and related matters.

8. Thereafter, the high level representatives of the Parties shall meet on an annual basis to discuss and review the implementation of and progress under this Agreement and related matters. Unless the Parties otherwise agree, the location of these annual meetings shall alternate between the United States and China. The Parties may convene additional technical or program-level meetings on an as-needed basis in any mutually agreeable location.

Article VIII

Performance Measures

1. The Parties shall collaboratively evaluate and discuss progress under this Agreement on an annual basis, including the effectiveness of the program, pursuant to the Annex.
2. HHS may base its evaluation of such progress on, among other things, the following:
 - a. the rate of refusal by HHS/FDA of Designated Covered Products exported from the customs territory of China and offered for import into the United States, as compared to the overall rate of refusal in calendar year 2007 or other relevant period by HHS/FDA of Designated Covered Products exported from the customs territory of China and offered for import into the United States;
 - b. the overall percentage of Designated Covered Products exported from the customs territory of China and offered for import into the United States that do not come from AQSIQ/CNCA Registered Establishments or are not certified; and
 - c. the volume, frequency and significance in terms of public health hazard of recalls of Designated Covered Products in the United States, including counterfeit Covered Products, exported from the customs territory of China and offered for import into the United States as compared to the volume, frequency and significance of such recalls in 2007 or other relevant period.

3. AQSIQ may base its evaluation of such progress on, among other things, the following:
 - a. the rate of refusal by AQSIQ of Designated Covered Products exported from the United States and offered for import into the customs territory of China, as compared to the overall rate of refusal in calendar year 2007 or other relevant period by AQSIQ of Designated Covered Products exported from the United States and offered for import into the customs territory of China;
 - b. the overall percentage of Designated Covered Products exported from the United States and offered for import into the customs territory of China that do not come from HHS/FDA Registered Establishments; and
 - c. the volume, frequency and significance in terms of public health hazard of recalls of Designated Covered Products in the customs territory of China, including counterfeit Covered Products, exported from the United States and offered for import into the customs territory of China as compared to the volume, frequency and significance of such recalls in 2007 or other relevant period.

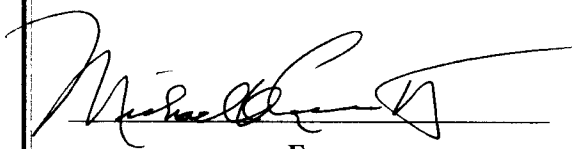
Article IX

Final Provisions

1. Nothing in this Agreement precludes the Government of the United States or the Government of China from taking any measure to protect the public health of the citizens of its respective country. Each Party affirms that it shall work with its country's national, state/provincial, or municipal bodies, as appropriate, to implement this Agreement fully.
2. Nothing in this Agreement shall be construed to affect the rights or obligations of the United States or China under any other agreement in force between the United States and China.
3. The Parties shall endeavor to resolve any dispute regarding the implementation or interpretation of this Agreement through timely consultations.

4. This Agreement shall enter into force upon signature by both Parties and shall remain in force for a period of five (5) years, unless terminated by either Party. On the last day of the five-year period, and of each subsequent five-year period, the Agreement shall automatically be renewed for another five-year period, unless either Party notifies the other Party that it wishes to terminate the Agreement at least sixty (60) calendar days prior to the last day of the relevant five year period. In addition, either Party may terminate the Agreement upon sixty (60) calendar days' written notice to the other Party. The Parties may amend the Agreement at any time, by mutual written agreement of the Parties.
5. All Annex provisions are incorporated in, and integral to, this Agreement. Each Party shall undertake all activities under this Agreement in accordance with its country's laws and regulations.

Done at Beijing, this 11th day of December, 2007, in duplicate in the English and Chinese languages, each text being equally authentic.



For
THE DEPARTMENT OF HEALTH AND
HUMAN SERVICES OF
THE UNITED STATES



For
THE GENERAL ADMINISTRATION
OF QUALITY SUPERVISION,
INSPECTION AND QUARANTINE OF
THE PEOPLE'S REPUBLIC OF CHINA

ANNEX

Section I. Determination of Designated Covered Products

Work under this Agreement will be implemented in a phased approach, beginning with an initial defined list of Designated Covered Products. The Parties shall conduct a formal evaluation of the outcomes of these programs for the initial Designated Covered Products. Based on the determination of the success of this first phase, the defined list of Designated Covered Products will be expanded to include additional Covered Products.

A. Factors

After consulting with each other, the Parties shall designate which Covered Products to include on the list of Designated Covered Products in each phase as appropriate based on the following factors:

- a. potential or actual, direct or indirect risk to the public health associated with the product, based on testing, inspection results or other information both Parties deem relevant;
- b. the rate of refusal by one Party of admission of the Covered Products into its territory or of problems associated with the Covered Products before, during or after entering the domestic commerce of the importing country, including product recalls, safety alerts, and enforcement actions;
- c. fraudulent or deceptive labeling or indications of any substitution or additions of a substance to a Covered Product or an ingredient of a Covered Product that reduces the quality of the ingredient or product or makes it appear of greater value than it is, without clearly revealing such substitution or addition to the recipient in the importing country; and
- d. the feasibility of implementing an effective and timely Work Plan with respect to the product.

B. First Phase - Designated Covered Products

1. The Parties agree that the following Covered Products, for which there are high import refusal rates and associated risk, shall be included in the first phase:
 - a. Low-acid canned products or acidified food;
 - b. Pet food/pet treats of plant origin or animal origin;
 - c. Ingredients of food and feed, i.e., wheat gluten and rice protein; and
 - d. All aquaculture farming products other than molluscan shellfish.

Details about these product categories will be further defined through the Work Plan agreed by the Parties.

2. Upon agreement, the Parties may designate additional Designated Covered Products for inclusion in any subsequent phase of the registration and certification programs. This process shall be detailed in the Work Plan.

Section II. Controls for Exports

1. The Parties acknowledge the successes of the AQSIQ/CNCA registration and certification programs in China, (e.g., in restoring confidence and improving the safety of ceramic ware imported from the customs territory of China). The Parties desire to build upon these successes of these long established programs to help ensure the safety of other food and feed imported from China.
2. Based on the success of the registration and certification programs, detailed below, HHS/FDA will use registration and certification information provided to it by AQSIQ to inform HHS/FDA import entry decisions, which may include a reduction in the rate of examination of Designated Covered Products that are part of the registration and/or certification program.

A. General

1. With respect to Covered Products that have been designated in accordance with Section I. A. of this Annex, AQSIQ/CNCA has already established and shall continue:
 - a. a registration program that requires all Establishments of Designated Covered Products for export from the customs territory of China to the United States to register with AQSIQ/CNCA; and
 - b. a certification program that is expanded to cover Designated Covered Products for export from the customs territory of China to the United States that provides for such products to be certified by AQSIQ as meeting HHS/FDA Requirements.
2. The Parties shall consult regarding the development of the registration and certification programs. These programs shall be implemented in phases and for the first phase shall cover the Designated Covered Products set forth in Section I.B.1 of this Annex and for subsequent phases shall cover the Covered Products as designated in accordance with Section I.A. of this Annex. The program shall expand to other products for subsequent phases contingent on the success of the preceding phase. In addition, based on the success of the preceding phase, the Parties may agree that with respect to a later phase that this Agreement shall be modified to include limitations on the export of any shipment of Designated Covered Products from the customs territory of China to the United States that AQSIQ has not certified as meeting HHS/FDA Requirements. The Parties may discuss in the future amending the Agreement to reflect the role of recognized third party testing and certification in promoting product safety.
3. HHS/FDA shall provide AQSIQ with copies of all relevant HHS/FDA Requirements, updated as appropriate, with respect to Designated Covered Products.

4. HHS/FDA shall promptly notify ASQIQ/CNCA about Designated Covered Products refused entry into the United States. Details for this notification system, including the timing and the mechanism, will be further defined in the Work Plan.
5. HHS/FDA commits to explore finding a mechanism to notify AQSIQ/CNCA about Designated Covered Products not accompanied by an AQSIQ/CIQ certificate.
6. Details for this notification system, including the timing and the mechanism, will be further defined in the Work Plan.
7. In the event that an Establishment shipping Designated Covered Products to the United States does not have an AQSIQ/CIQ certificate or in the event that a shipment of Designated Covered Product offered for import into the United States is not accompanied by an AQSIQ/CIQ certificate, and HHS/FDA deems that Establishment or shipment meets HHS/FDA Requirements, HHS/FDA shall notify AQSIQ and the Parties shall discuss the situation, as warranted.

B. Registration

1. With regard to Designated Covered Products for shipment to the United States, AQSIQ/CNCA shall:
 - a. ensure it registers only Establishments that meet HHS/FDA Requirements;
 - b. monitor each AQSIQ/CNCA Registered Establishment to ensure that it continues to meet HHS/FDA Requirements; and
 - c. ensure each AQSIQ/CNCA Registered Establishment is informed of all applicable HHS/FDA Requirements.
2. Pursuant to the program maintained in accordance with Section I.A.1 of this Annex, AQSIQ shall require that all Establishments of Designated Covered Products for export to the United States register with AQSIQ/CNCA. Each registration shall include the following:
 - a. the name and address of the Establishment;

- b. a list of all Designated Covered Products associated with the Establishment;
and
 - c. the name and contact information (including phone number) of the owner, manager, or other senior official responsible at the Establishment.
3. AQSIQ/CNCA shall require AQSIQ/CNCA Registered Establishments to inform ASQIQ/CNCA upon any changes in the information provided in its registration and to provide updated information.
 4. AQSIQ/CNCA shall conduct annual inspections of all AQSIQ/CNCA Registered Establishments to ensure each AQSIQ/CNCA Registered Establishment meets HHS/FDA Requirements. AQSIQ/CNCA shall inspect each AQSIQ/CNCA Registered Establishment within 180 calendar days of the date of registration as a baseline for annual inspections thereafter. AQSIQ/CNCA shall revoke or suspend the registration of any Establishment that it determines, as a result of an inspection or otherwise, does not meet HHS/FDA Requirements.
 5. AQSIQ/CNCA shall provide HHS/FDA a list of all AQSIQ/CNCA Registered Establishments, and the Designated Covered Products of each such Establishment ("List of AQSIQ/CNCA Registered Establishments"), via a secure electronic system. AQSIQ/CNCA shall provide HHS/FDA the first List of AQSIQ/CNCA Registered Establishments within thirty (30) calendar days of the date of entry into force of this Agreement, and shall update the list every ninety (90) calendar days from the date it provides the first List of AQSIQ/CNCA Registered Establishments.
 6. Within fifteen (15) calendar days of receiving the List of AQSIQ/CNCA Registered Establishments or any updates, HHS/FDA shall publish it on its website.
 7. HHS/FDA shall provide AQSIQ/CNCA a list of all Establishments registered with HHS/FDA. HHS/FDA shall provide this list to AQISQ/CNCA, via a secure electronic system, within thirty (30) calendar days of the date of entry

into force of this Agreement, and shall update the list every ninety (90) calendar days from the date it provides the first list of AQSIQ/CNCA Registered Establishments.

8. AQSIQ/CNCA shall notify HHS/FDA in writing of all AQSIQ/CNCA Registered Establishments that have failed inspection or whose registration AQSIQ/CNCA has suspended, revoked or denied and the reasons therefor. AQSIQ/CNCA shall provide HHS/FDA this information, including a description of the problems identified, within two (2) calendar days of the failure, denial, revocation, or suspension, via secure electronic transmission.
9. AQSIQ/CNCA shall require AQSIQ/CNCA Registered Establishments to notify AQSIQ/CNCA within three (3) calendar days of detection of any failure to meet HHS/FDA Requirements or of any contamination, major defect, or any other safety concern with regard to a Covered Product for export to the United States. AQSIQ/CNCA shall transmit any such notification to HHS/FDA within three (3) calendar days of the time AQSIQ/CNCA receives it. HHS/FDA shall transmit such notification to the U.S. Department of Homeland Security's Customs and Border Protection as appropriate.
10. AQSIQ shall ensure it has and uses a system to enable the tracing of Designated Covered Products from the source of production or manufacture to exportation to assist in containing and resolving safety problems. AQSIQ shall cooperate with HHS/FDA to ensure that AQSIQ's system is effective. The Work Plan shall further specify the forms or specific types of cooperation to be undertaken.
11. AQSIQ/CNCA shall maintain documents on file related to reviews, inspections, testing, recalls, compliance, and any other assessment of a AQSIQ/CNCA Registered Establishment. AQSIQ/CNCA shall make such records available to HHS/FDA within five (5) calendar days of an HHS/FDA request.

12. Upon agreement by both Parties, AQSIQ shall facilitate periodic audits or reviews of the AQSIQ/CNCA registration program by HHS/FDA.

C. Certification

1. If the China Entry-Exit Inspection and Quarantine Bureau ("AQSIQ/CIQ") determines a shipment meets HHS/FDA Requirements, it shall issue a certificate that contains a unique identifying number and attests that the shipment meets HHS/FDA Requirements. AQSIQ/CIQ shall issue a certificate for a shipment of Designated Covered Products for export to the United States only if such shipment meets HHS/FDA Requirements.
2. To avoid counterfeiting of certificates or the falsification of information, within sixty (60) calendar days of the date of entry into force of this Agreement, AQSIQ and HHS/FDA shall designate technical experts to work together to develop the technological capabilities to implement a secure electronic system or other secure means to transmit certificate and to receive information.
3. Once the secure electronic system is established, AQSIQ/CIQ shall provide HHS/FDA a copy of each certificate issued pursuant to the certification program maintained pursuant to Section II.A.1.b. of this Annex via a secure electronic transmission within three (3) calendar days of the issuance of the certificate. AQSIQ should notify the exporter of the shipment for which AQSIQ issued the certificate that it should provide the certificate's unique identifying number to the importer of record in the United States, or to any intermediate party responsible for transmitting entry filing information to the importer of record in the United States. AQSIQ should notify the exporter or intermediate party that it should provide the unique identifying number electronically to the United States customs authorities along with the entry filing for each shipment.

4. AQSIQ shall immediately revoke a certificate of any shipment of Designated Covered Products for export to the United States if it determines that a shipment does not meet HHS/FDA Requirements. AQSIQ may base a revocation of a certificate on inspection or testing results or any other information that comes to the attention of Chinese or United States authorities to indicate that the product does not meet HHS/FDA Requirements. AQSIQ shall notify HHS/FDA of any revocation with three (3) calendar days of the revocation.
5. Upon agreement by both Parties, AQSIQ shall facilitate periodic audits or reviews of the AQSIQ certification program by HHS/FDA.
6. AQSIQ shall monitor the safety of Designated Covered Products by conducting a testing program that provides, as determined by HHS/FDA, a high level of statistical confidence in the quality of such products offered for import into the United States.

D. Additional Provisions

1. HHS/FDA may request AQSIQ to conduct an investigation regarding any Covered Products exported from the customs territory of China that HHS/FDA has reason to believe may pose a health or safety risk to public health or safety of U.S. citizens. AQSIQ shall respond to HHS/FDA within three (3) calendar days of receipt of the request and shall promptly conduct a thorough investigation. With regard to AQSIQ/CNCA Registered Establishments, AQSIQ shall notify HHS/FDA within fifteen (15) calendar days of an inspection request of:
 - a. information relating to the source of the health or safety risk;
 - b. the steps taken to remedy the risk; and
 - c. the outcome of any remediation.

With regard to non-AQSIQ/CNCA Registered Establishments, AQSIQ shall notify HHS/FDA of the above information as soon as it becomes available.

2. AQSIQ shall inform HHS/FDA of the results of its investigation within three (3) calendar days of completing its investigation. The Work Plan shall further detail requirements and performance measures related to requested investigations.
3. Upon the agreement of AQSIQ/CNCA, HHS/FDA may participate fully in any annual or other AQSIQ inspection of any AQSIQ/CNCA Registered Establishment.
4. HHS/FDA will consult with AQSIQ/CNCA, and shall be permitted to conduct an inspection of any AQSIQ/CNCA Registered Establishment within five (5) calendar days of notifying AQSIQ. AQSIQ shall facilitate HHS/FDA's inspection, including by ensuring, at HHS/FDA's request, that such inspections are conducted without providing advance notice to the AQSIQ/CNCA Registered Establishment.
5. Upon the agreement of HHS/FDA, AQSIQ/CNCA may conduct an audit of any refusal of a Covered Product within five (5) calendar days of notifying HHS/FDA. HHS/FDA shall facilitate AQSIQ/CNCA's audit including by providing relevant information at AQSIQ/CNCA's request (e.g., the test methods and procedures as well as test results.)
6. To the extent possible, HHS/FDA shall notify AQSIQ/CNCA of significant potential negative impact, based on scientific investigation, on human or animal health relating to food and feed imported from the customs territory of China as soon as HHS/FDA becomes aware that there may be a link with a product imported from the customs territory of China. The Parties shall discuss the data in an effort to better understand the situation.
7. For any shipment of Covered Products for export to the United States that AQSIQ determines does not meet, or appears not to meet, HHS/FDA Requirements, or if AQSIQ obtains information or has other reason to believe that a shipment poses a risk to public health, AQSIQ shall notify HHS/FDA in writing, including the reasons therefor and other information that may assist in

HHS/FDA in identifying the shipment and the supplier, within three (3) calendar days of its determination.

8. In addition to other provisions of this Agreement, AQSIQ shall not permit the export to the United States of any Covered Product that it has evidence is unsafe.
9. Except in extraordinary circumstances, each Party shall observe the following procedures: Each Party shall publish on its website and in the relevant government publication (i.e., HHS/FDA, the Federal Register; AQSIQ, the Ministry of Commerce of People's Republic of China (MOFCOM) Gazette), all proposed regulations and other measures related to Designated Covered Products and allow a reasonable period of time for all interested parties to submit comments. Each Party shall consider such comments and, at the time it adopts final regulations, address in writing significant, substantive comments received from interested persons during the comment period and explain any substantive revision made to the proposed regulations. Each Party shall also publish on its website, and in the relevant government publication, all final regulations, and measures related to Designated Covered Products and allow a reasonable amount of time before implementation and enforcement.